

## **IC 16-42**

# **ARTICLE 42. REGULATION OF FOOD, DRUGS, AND COSMETICS**

## **IC 16-42-1**

Chapter 1. Uniform Food, Drug, and Cosmetic Act: General Provisions

### **IC 16-42-1-1**

#### **Purpose of act**

Sec. 1. (a) IC 16-42-1 through IC 16-42-4 are intended to safeguard the public health and promote the public welfare by protecting the:

(1) consuming public from injury by product use; and  
(2) purchasing public from injury by merchandising deceit; flowing from intrastate commerce in food, drugs, devices, and cosmetics.

(b) IC 16-42-1 through IC 16-42-4 are intended to be uniform with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and with the Federal Trade Commission Act (15 U.S.C. 41 et seq.) to the extent they expressly outlaw the false advertisement of food, drugs, devices, and cosmetics.

(c) IC 16-42-1 through IC 16-42-4 thus promote uniformity of such statutes and their administration and enforcement throughout the United States.

*As added by P.L.2-1993, SEC.25.*

### **IC 16-42-1-1.1**

#### **Duties of state veterinarian and state board of animal health**

Sec. 1.1. (a) The state veterinarian shall act in place of the state health commissioner under this chapter when impounding or disposing of adulterated or misbranded products under IC 15-2.1-23 or IC 15-2.1-24.

(b) The Indiana state board of animal health shall act in place of the state department of health under this chapter when impounding or disposing of adulterated or misbranded products under IC 15-2.1-23 or IC 15-2.1-24.

*As added by P.L.137-1996, SEC.68.*

### **IC 16-42-1-2**

#### **Authority to adopt certain federal regulations**

Sec. 2. The purpose of IC 16-42-1 through IC 16-42-4 being to promote uniformity with the Federal Act, in safeguarding the public health and in promoting public welfare, the state department may adopt, insofar as applicable, the regulations promulgated under the Federal Act and the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

*As added by P.L.2-1993, SEC.25.*

**IC 16-42-1-3****Adoption of regulations; notice and hearing**

Sec. 3. Except to the extent that the state department adopts the applicable regulations promulgated by the federal security administrator under the Federal Act (21 U.S.C. 301 et seq.), the state department, before adopting a rule contemplated by section 6 or 9 of this chapter, IC 16-42-2-1, IC 16-42-2-3(11), IC 16-42-3-4(4), IC 16-42-3-4(6), IC 16-42-3-4(7), or IC 16-42-3-4(8) shall give appropriate notice of the proposal and of the time and place for a public hearing to be held as provided by law.

*As added by P.L.2-1993, SEC.25.*

**IC 16-42-1-4****Construction of act and rules**

Sec. 4. IC 16-42-1 through IC 16-42-4 and rules adopted under those provisions shall, insofar as applicable, be interpreted and construed to effectuate the general purpose to enact state legislation uniform with the Federal Act (21 U.S.C. 301 et seq.).

*As added by P.L.2-1993, SEC.25.*

**IC 16-42-1-5****Federal agency references; successor agency**

Sec. 5. Whenever this chapter refers to a department or an agency of the federal government, the term includes a department or an agency of the federal government to which the duties, powers, or functions are transferred or given.

*As added by P.L.2-1993, SEC.25.*

**IC 16-42-1-6****Registration of manufacturer, processor, repackager, or wholesale distributor; maintaining place of business in state**

Sec. 6. (a) A manufacturer, processor, repackager, or wholesale distributor of food, drugs, or cosmetics who maintains a place of business in Indiana shall file with the state department, upon forms to be furnished by the state department, a written statement of the name and address of the owner, the character of the business, and the business address of each place of business in Indiana.

(b) A new place of business for the manufacture, processing, repacking, or wholesale distribution of food, drugs, or cosmetics may not be established in Indiana until the place of business has been registered as provided in this chapter.

(c) If ownership of a registered place of business changes, the new owner shall reregister the place of business before operating the same.

*As added by P.L.2-1993, SEC.25.*

**IC 16-42-1-7****Misleading advertising or labeling; evaluation of representations**

Sec. 7. If:

(1) an article is alleged to be misbranded because the labeling

is misleading; or

(2) an advertisement is alleged to be false because the advertisement is misleading;

in determining whether the labeling or advertisement is misleading, there shall be taken into account among other items not only representations made or suggested by statement, word, design, device, sound, or any combination of those methods, but also the extent to which the labeling or advertisement fails to reveal facts that are material in the light of representations or that are material with respect to consequences that may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement or under conditions of use that are customary or usual.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-8**

##### **Labeling requirements; visibility**

Sec. 8. A labeling requirement under IC 16-42-1 through IC 16-42-4 is not considered to be complied with unless:

(1) the word, statement, or other information appearing on the label also appears on the outside container or wrapper, if any, of the retail package of the article; or

(2) the word, statement, or other information appearing on the label is easily seen through the outside container or wrapper.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-9**

##### **Advertisements; curative or therapeutic effect for certain diseases**

Sec. 9. (a) This section does not apply to an advertisement that:

(1) is disseminated only to members of the medical, dental, pharmaceutical, and other legally recognized professions dealing with the healing arts;

(2) appears only in the scientific periodicals of those professions; or

(3) is disseminated only for the purpose of public health education by persons not commercially interested in the sale of such drugs or devices.

(b) The advertisement of a drug or device that represents that the drug or device has any effect in:

albuminuria	mumps
appendicitis	nephritis
arteriosclerosis	otitis media
blood poison	paralysis
bone disease	pneumonia
Bright's disease	poliomyelitis (infantile
cancer paralysis)	
carbuncles	prostate gland disorders
cholecystitis	pyelitis
diabetes	scarlet fever
diphtheria	sexual impotence

dropsy	sinus infection	
erysipelas		smallpox
gallstones		tuberculosis
heart and vascular		tumors
diseases		typhoid
high blood pressure		uremia
mastoiditis		venereal disease
measles		meningitis

is considered false for purposes of IC 35-43-5-3.

(c) Whenever the state department determines that an advance in medical science has made a type of self medication safe as to any of the diseases listed in this section, the state department shall adopt rules to authorize the advertisement of drugs having curative or therapeutic effect for the disease, subject to conditions and restrictions the state department considers necessary in the interests of public health.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-10**

##### **Samples or specimen; investigation and examination**

Sec. 10. The state department shall cause the investigation and examination of food, drugs, devices, and cosmetics subject to IC 16-42-1 through IC 16-42-4. The state health commissioner or the commissioner's authorized representative may do the following:

- (1) Take a sample or specimen of any such merchandise, for examination under IC 16-42-1 through IC 16-42-4, upon tendering the market price to the person having the merchandise in custody.
- (2) Enter any place, establishment, or vehicle in Indiana at reasonable times for the purpose of taking a sample or specimen of merchandise for examination.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-11**

##### **Inspection of records**

Sec. 11. For the purpose of enforcing IC 16-42-1 through IC 16-42-4, pertinent records of an administrative agency of the state are open to inspection by the state health commissioner or the commissioner's authorized representative.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-12**

##### **Access to and copying of records; use of evidence**

Sec. 12. (a) For the purpose of enforcing IC 16-42-1 through IC 16-42-4, carriers engaged in commerce, and persons receiving food, drugs, devices, or cosmetics in commerce or holding such articles so received shall, upon the request of an officer or employee designated by the state department, permit the officer or employee, at reasonable times, to have access to and to copy all records showing the movement in commerce of any food, drug, device, or

cosmetic, or the holding of a food, drug, device, or cosmetic during or after the movement, and the quantity, shipper, and consignee of the food, drug, device, or cosmetic.

(b) It is unlawful for a carrier or person described in subsection (a) to fail to permit access to and copying of such records upon request if the request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which the request relates.

(c) Evidence obtained under this section may not be used in a criminal prosecution of the person from whom the evidence is obtained.

*As added by P.L.2-1993, SEC.25.*

### **IC 16-42-1-13**

#### **Inspection of factories, warehouses, and vehicles**

Sec. 13. For the purpose of enforcing IC 16-42-1 through IC 16-42-4, the state health commissioner or the commissioner's authorized representative may do the following:

(1) Enter, at reasonable times any factory, warehouse, place of production, or establishment subject to IC 16-42-1 through IC 16-42-4 or enter any vehicle being used to transport or hold food, drugs, devices, or cosmetics.

(2) Inspect at reasonable times, the factory, warehouse, place of production, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, labeling, and advertisements.

*As added by P.L.2-1993, SEC.25.*

### **IC 16-42-1-14**

#### **Report of judgments, orders, and decrees**

Sec. 14. The state health commissioner or the commissioner's legally authorized agent may periodically publish reports summarizing all judgments, decrees, and court orders given under IC 16-42-1 through IC 16-42-4, including the nature of the charge and the disposition of the charge.

*As added by P.L.2-1993, SEC.25.*

### **IC 16-42-1-15**

#### **Dissemination of information**

Sec. 15. (a) The state health commissioner or the commissioner's legally authorized agent may cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the state health commissioner or the commissioner's legally authorized agent, imminent danger to health or gross deception of, or fraud upon, the consumer.

(b) This section does not prohibit the state health commissioner or the commissioner's legally authorized agent from collecting, reporting, and illustrating the results of the commissioner's examinations and investigations under IC 16-42-1 through IC 16-42-4.

*As added by P.L.2-1993, SEC.25.*

## **IC 16-42-1-16**

### **Prohibited acts; defenses; injunctions**

Sec. 16. (a) A person may not engage in any of the following acts:

- (1) The sale in intrastate commerce of a food, drug, device, or cosmetic that is adulterated or misbranded.
- (2) The adulteration or misbranding of a food, drug, device, or cosmetic in intrastate commerce.
- (3) The receipt in intrastate commerce of a food, drug, device, or cosmetic that is adulterated or misbranded, and the sale of those items in intrastate commerce for pay or otherwise.
- (4) The sale of any article in violation of IC 16-42-1-6, IC 16-42-3-7, IC 16-42-3-8, IC 16-42-3-9, or IC 16-42-3-10.
- (5) The refusal to permit access to or copying of any record as required by section 12 of this chapter.
- (6) The refusal to permit entry or inspection and collecting of samples as authorized by section 10 or 13 of this chapter.
- (7) The use, without proper authority, of any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this chapter or IC 16-42-2 through IC 16-42-4.
- (8) The use by any person to the person's own advantage, or the revelation, other than to the state health commissioner or the state health commissioner's authorized representative or to the courts when relevant in any judicial proceeding, any information acquired under authority of section 13 of this chapter or IC 16-42-3-7 through IC 16-42-3-10 concerning any method or process that as a trade secret is entitled to protection.
- (9) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic if the act is done while the article is held for sale and results in the article being misbranded.
- (10) The use on the labeling of any drug or in any advertising relating to the drug of any representation or suggestion that an application with respect to the drug is effective under IC 16-42-3-7 and IC 16-42-3-8 unless the drug complies with those sections.
- (11) The removal or disposal of a detained or embargoed article in violation of this chapter.
- (12) The giving of a guaranty or undertaking in intrastate commerce referred to in subsection (c) that is false.

(b) A person who violates subsection (a) commits a Class A misdemeanor. However, the offense is a Class D felony if the offense is committed with intent to defraud or mislead.

(c) It is a defense for a person accused of violating subsection (a)(1) or subsection (a)(3) if the person establishes a guaranty or undertaking signed by and containing the name and address of the person residing in the United States from whom the accused person

received in good faith the article to the effect that the article is not adulterated or misbranded within the meaning of this article or the Federal Act.

(d) In addition to the remedies provided in this article, the state health commissioner or the commissioner's legally authorized agent may apply to the circuit or superior court for a temporary or permanent injunction restraining any person from violating any provision of this section.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-17**

##### **Schedule of civil penalties; order of compliance; consolidation of proceedings**

Sec. 17. (a) In addition to the other remedies provided in this article, the state department shall adopt a schedule of civil penalties that may be levied to enforce the following:

(1) This chapter, IC 16-42-2-6, IC 16-42-2-7, and IC 16-42-18.

(2) The rules adopted under this chapter, IC 16-42-2-6, IC 16-42-2-7, and IC 16-42-18 by the state department.

(b) A penalty included in the schedule of civil penalties adopted under subsection (a) may not exceed one thousand dollars (\$1,000) for each violation per day.

(c) The state department may issue an order of compliance, impose a civil penalty included in the schedule of civil penalties adopted under subsection (a), or both, against a person who does any of the following:

(1) Fails to comply with this chapter, IC 16-42-2-6, IC 16-42-2-7, or IC 16-42-18 or a rule adopted under this chapter, IC 16-42-2-6, IC 16-42-2-7, or IC 16-42-18.

(2) Interferes with or obstructs the state department in the performance of duties under this chapter, IC 16-42-2-6, IC 16-42-2-7, or IC 16-42-18.

(d) An order of compliance may be issued under IC 4-21.5-3-6, IC 4-21.5-3-8, or IC 4-21.5-4. A civil penalty may be imposed only in a proceeding under IC 4-21.5-3-8.

(e) A proceeding commenced to impose a civil penalty may be consolidated with any other proceeding commenced to enforce any of the following:

(1) This chapter, IC 16-42-2-6, IC 16-42-2-7, or IC 16-42-18.

(2) A rule adopted under this chapter, IC 16-42-2-6, IC 16-42-2-7, or IC 16-42-18.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-18**

##### **Embargo or detention of adulterated or misbranded merchandise; tagging or marking**

Sec. 18. (a) Whenever a duly authorized agent of the state department finds or has probable cause to believe that any food, drug, device, or cosmetic is:

(1) adulterated; or

(2) so misbranded as to be dangerous or fraudulent;  
within the meaning of IC 16-42-1 through IC 16-42-4, the state health commissioner or the commissioner's legally authorized agent shall affix to the merchandise a tag or other appropriate marking as described in subsection (b).

(b) The tag or marking required in subsection (a) must do the following:

(1) Give notice that the merchandise is or is suspected of being adulterated or misbranded.

(2) Give notice that the merchandise has been detained or embargoed as follows:

(A) Five (5) days in the case of food.

(B) Ten (10) days in the case of drugs and cosmetics.

(3) Contain a warning to all persons not to remove or dispose of the merchandise by sale or otherwise until permission for removal or disposal is given by the state department or the court.

(c) A person may not remove or dispose of detained or embargoed merchandise by sale or otherwise without permission of the state department or the court.

(d) The claimant may, under the supervision of the state department, destroy the detained merchandise.

(e) If the state department finds that merchandise that has been detained or embargoed is not adulterated or misbranded, the state department shall remove the tag or marking.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-19**

##### **Condemnation of detained or embargoed merchandise; petition**

Sec. 19. (a) When merchandise detained or embargoed under section 18 of this chapter has been found by the state department to be adulterated or misbranded, the state department shall within five (5) days cause to be filed a petition in any circuit or superior court in whose jurisdiction the merchandise is detained or embargoed for condemnation of the merchandise as provided in this chapter.

(b) The proceedings shall be brought in the name of the state by the prosecuting attorney of the county in which a violation occurs against the merchandise, and the petition shall be verified by the state department. The petition must do the following:

(1) Describe the merchandise.

(2) State the location of the merchandise.

(3) State the name of the person, firm, limited liability company, or corporation in actual possession.

(4) State the name of the owner, if known, to the state department.

(5) Allege the particular violation that is claimed to exist.

(6) Otherwise conform to the requirements of a petition for condemnation of an adulterated or misbranded food, drug, device, or cosmetic in the United States courts.

*As added by P.L.2-1993, SEC.25. Amended by P.L.8-1993, SEC.252.*



**IC 16-42-1-20****Seizure and destruction of embargoed or detained merchandise**

Sec. 20. (a) Upon the filing of a petition for condemnation of an adulterated or misbranded food, drug, device, or cosmetic, the court shall promptly cause process to issue to the appropriate law enforcement agency commanding the law enforcement agency to seize the merchandise described in the court order and to hold the goods for further order of the court.

(b) The appropriate law enforcement agency shall, at the time of seizure of goods under this section, serve a copy of the process upon the owner of the merchandise.

(c) At the expiration of thirty (30) days after the seizure of merchandise under this section, if no claimant has appeared to defend against the petition, the court shall order the appropriate law enforcement agency to destroy the seized merchandise.

*As added by P.L.2-1993, SEC.25.*

**IC 16-42-1-21****Filing of answer or demurrer**

Sec. 21. A person:

(1) having an interest in the alleged adulterated or misbranded foods, drugs, devices, or cosmetics; or

(2) against whom a civil or criminal liability would exist if the merchandise is adulterated or misbranded;

may, at any time before destruction of the merchandise, appear and file answer or demurrer to the petition. Such appearance and answer or demurrer shall be filed in open court, or if in vacation, with the clerk or judge of the court. The answer or demurrer must allege the interest or liability of the party filing it. In all other respects, the issues shall be raised as in other civil actions.

*As added by P.L.2-1993, SEC.25.*

**IC 16-42-1-22****Rights of litigants**

Sec. 22. The right of change of venue from the county, the right of change of judge, and the right of trial by jury are the same as in civil cases.

*As added by P.L.2-1993, SEC.25.*

**IC 16-42-1-23****Election to divide libeled merchandise into lots; dismissal as to particular lots; consent to destruction of particular lots**

Sec. 23. (a) At any time before trial, the defense may file with the court a written election to divide into lots the merchandise that is alleged to be adulterated or misbranded. Each of the lots must be described in the written election in such a way as to enable them to be distinguished.

(b) If different parties are defending as to separate lots, the court shall proceed to docket as many separate actions as there are separate defendants.

(c) The state department may dismiss as to any lot without prejudice to the proceeding against all other lots in the same seizure. Those defending may consent to the destruction of any lot without prejudice to their right to defend against the condemnation of all other lots in the same seizure.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-24**

##### **Judgment**

Sec. 24. The court or jury trying the cause shall determine and the judgment shall specify whether the contents of each separate lot are adulterated or misbranded. The court shall order the destruction by the appropriate law enforcement agency of all lots found to be adulterated or misbranded and the return by the appropriate law enforcement agency of all lots not found to be adulterated or misbranded.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-25**

##### **Judgment for costs**

Sec. 25. (a) A personal judgment may not be given against a defendant, except as provided in subsection (b).

(b) When merchandise is ordered destroyed, the court may give judgment against the defendant for that part of the costs occasioned by the defendant.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-26**

##### **Return of libeled merchandise; liability for damages**

Sec. 26. (a) Whenever the court orders the return of merchandise, the appropriate law enforcement agency shall immediately return the merchandise to the place of seizure. The appropriate law enforcement agency and the appropriate law enforcement agency's bondsmen are liable for any damage to the merchandise while in the custody of the appropriate law enforcement agency if the damage was due to negligence, willfulness, or carelessness upon the part of the appropriate law enforcement agency or the appropriate law enforcement agency's agents.

(b) No subsequent proceeding in the cause or new trial may in any way involve any returned merchandise.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-27**

##### **New trial; appeal; appeal bond**

Sec. 27. (a) A defendant may move for a new trial and may appeal to the supreme court or the court of appeals in the manner provided by law for appeals in civil actions.

(b) An appeal bond shall be fixed in an amount that covers the reasonable costs of preserving the condemned merchandise for the probable time of appeal and the court costs.

(c) If an appeal is not prosecuted to determination or if the judgment of the trial court is affirmed, the defendant bringing the appeal is liable for the following:

(1) The costs adjudged against the defendant or defendants in the trial court.

(2) The costs of appeal.

(3) The actual reasonable cost of preserving the condemned merchandise during the appeal period.

(d) The court of appeals and the supreme court shall dispose of appeals brought under this chapter as speedily as possible with due regard to the rights of the parties involved.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-28**

##### **Judgment as evidence**

Sec. 28. A judgment in a condemnation proceeding under this chapter is not admissible as evidence in any other legal proceeding.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-29**

##### **Costs not adjudicated against defendants**

Sec. 29. All costs not adjudicated against the defendants in accordance with this chapter are to be determined and collected in the manner provided by law for the determination and collection of costs in unsuccessful criminal prosecutions.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-30**

##### **Libel for condemnation; procedure**

Sec. 30. Except as otherwise provided in this chapter, the procedure for condemnation proceedings under this chapter must conform, as nearly as possible, to the procedure for civil actions.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-31**

##### **Destruction of adulterated or misbranded products; expenses**

Sec. 31. (a) If the court finds that detained or embargoed merchandise is adulterated or misbranded, the merchandise must, after entry of the judgment or decree, be destroyed at the expense of the claimant, under the supervision of the state department.

(b) All:

(1) court costs and fees; and

(2) storage and other proper expenses;

shall be taxed against the claimant of the merchandise or the claimant's agent.

(c) If the adulteration or misbranding of merchandise can be corrected by proper labeling or processing of the merchandise, the court may order the merchandise to be delivered to the claimant for labeling or processing under the supervision of the state department under the following conditions:

- (1) After entry of the decree or judgment.
- (2) After costs, fees, and expenses have been paid.
- (3) After sufficient bond, conditioned that the merchandise be so labeled or processed, is executed.

The expense of the supervision of labeling and processing shall be paid by the claimant. The bond shall be returned to the claimant of the merchandise on representation to the court by the state health commissioner or the commissioner's legally authorized agent that the merchandise no longer violates IC 16-42-1 through IC 16-42-4 and that the expenses of supervision by the state department have been paid.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-32**

##### **Notice and opportunity for hearing preceding criminal prosecution**

Sec. 32. Before any violation of IC 16-42-1 through IC 16-42-4 is reported by the state health commissioner or the commissioner's authorized agent to a prosecuting attorney for the institution of a criminal proceeding, the person against whom the proceeding is contemplated shall be given appropriate notice and an opportunity to present the person's views to the state health commissioner or the commissioner's authorized agent, either orally or in writing, with regard to the contemplated proceeding.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-33**

##### **Minor violations**

Sec. 33. IC 16-42-1 through IC 16-42-4 does not require the state health commissioner or the commissioner's authorized agent to report, for the institution of proceedings under those provisions, minor violations of those provisions whenever the state health commissioner or the commissioner's legally authorized agent believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

*As added by P.L.2-1993, SEC.25.*

#### **IC 16-42-1-34**

##### **Chapter violations; offenses**

Sec. 34. (a) Except as otherwise provided, a person who recklessly violates or fails to comply with this chapter commits a Class B misdemeanor.

(b) Each day a violation continues constitutes a separate offense.

*As added by P.L.2-1993, SEC.25.*